IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

THE STATE OF TEXAS, *ex rel.* ALLISON ZAYAS and TRACY MIKSELL-BRANCH, Plaintiffs, V. ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P., Defendants.	§ § § § § § § § § § §	1-14-CV-1111 RP

ORDER

Before the Court are Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447, filed January 9, 2015 (Clerk's Dkt. #17); Memorandum in Opposition to Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447, filed January 30, 2015 (Clerk's Dkt. #28); Plaintiffs' Reply to Defendants' Opposition to Motion to Remand, filed February 10, 2015 (Clerk's Dkt. #30); and Sur-Reply to Plaintiffs' Reply to Defendants' Opposition to Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447, filed February 20, 2015 (Clerk's Dkt. #33). After reviewing the parties' pleadings, relevant case law, as well as the entire case file, the Court issues the following order.

I. BACKGROUND

Plaintiffs the State of Texas, by and through the Attorney General of Texas, and relators Allison Zayas and Tracy Miksell-Branch originally filed this action in the 353rd Judicial District Court of Travis County, Texas on October 10, 2013. They named as defendants Astrazeneca, L.P., and Astrazeneca Pharmaceuticals, L.P. (jointly "AstraZeneca").

Plaintiffs contend Defendants entered into a long-term, multi-year scheme to improperly promote the use of two drugs manufactured by AstraZeneca, Seroquel IR and Seroquel XR (jointly the "Seroquel Franchise"). According to Plaintiffs, Defendants became aware in 2006 that they

were under investigation for unlawful promotion of Seroquel IR for off-label use in depression and for children and adolescents.[1] Plaintiffs allege Defendants, while entering into settlement negotiations to resolve the investigation, simultaneously continued their improper promotion of off-label uses of the Seroquel Franchise.[2] Plaintiffs contend Defendants provided incorrect information regarding the drugs and their side effects, constituting "misbranding" under federal law. Plaintiffs additionally allege Defendants paid illegal kickbacks to decision-makers within the Texas medical community. Plaintiffs assert, "[s]imply put, Defendant prioritized increasing sales figures over complying with federal and state regulations." (Plf. 1st Am. Pet. ¶ 72). Plaintiffs maintain the improper conduct of Defendants resulted in excessive reimbursements for the Seroquel Franchise by the Texas Medicaid program.

Plaintiffs assert solely state law causes of action, specifically violation of the Texas Medicaid Fraud Prevention Act, common law fraud, aiding and abetting breach of fiduciary duty, negligent misrepresentation, monies had and received and promissory estoppel, alleging Defendants acted improperly for the purpose of receiving benefits under the Texas Medicaid program. (Plf 1st Am. Pet. ¶¶ 121-61).

Defendants removed the action to this Court, asserting federal question jurisdiction, following the filing of Plaintiffs' First Amended Petition in state court. Plaintiffs have now filed a motion to remand this action back to state court. The parties have filed responsive pleadings and the motion is ripe for review.

II. STANDARD OF REVIEW

Federal courts have original jurisdiction over cases "arising under the Constitution, treaties

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[1] Pharmaceuticals are approved by the Federal Drug Administration ("FDA") for specific uses. Uses for other purposes are referred to as "off-label."

[2] According to Plaintiffs, in 2010 Defendants agreed to pay $520 million for dismissal of the claims associated with the investigation. (Plf. 1st Am. Pet. ¶ 64, citing http://www.justice.gov/opa/pr/2010/April/10-civ-487.html).

or laws of the United States." 28 U.S.C. § 1331. A case may be removed to federal court if the action is one over which the federal court possesses subject matter jurisdiction. 28 U.S.C. § 1441(a). Implementation of this statute is controlled by the well-pleaded complaint rule. This rule provides that a "properly pleaded complaint governs the jurisdictional determination and if, on its face, such a complaint contains no issue of federal law, then there is no federal question jurisdiction." *Aaron v. Nat'l Union Fire Ins. Co.*, 876 F.2d 1157, 1160-61 (5th Cir. 1989). Stated differently, removal is proper if the complaint establishes: (1) federal law creates the cause of action; or (2) federal law is a necessary element of one of the well-pleaded claims. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808-09 (1988); *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983). When the propriety of removal is challenged, the burden of establishing federal jurisdiction is on the party who removed the action. *Miller v. Diamond Shamrock Co.*, 275 F.3d 414, 417 (5th Cir. 2001); *Frank v. Bear Stearns & Co.*, 128 F.3d 919, 921-22 (5th Cir. 1997).

II. DISCUSSION

The parties here agree Plaintiffs are asserting claims which are created by state law, rather than federal law. Defendants nonetheless maintain removal was proper because the claims fall into a "special and small category" of cases "in which arising under jurisdiction still lies" because the case raises a federal issue. *Gunn v. Minton*, __ U.S. __, 133 S. Ct. 1059, 1064-65 (2013); *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 699 (2006). Specifically, federal jurisdiction over a state law claim will lie "if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 133 S. Ct. at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)). The Fifth Circuit states the inquiry as whether "(1) resolving the federal issue is necessary to resolution of the state-law claim;

(2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008).

The threshold for this inquiry is identification of the federal issue underlying the asserted state law claims. In removing this action, Defendants pointed out that Plaintiffs' state court petition describes the FDA's regulatory scheme in detail and the prohibitions under the Food, Drug and Cosmetics Act ("FDCA") against "misbranding" of prescription drugs, as well as the federal statutory scheme for prescription drug reimbursement by Medicaid. Defendants maintain in the notice of removal that federal jurisdiction lies because the theory underlying all of Plaintiffs' claims rests on federal law. As our sister court has noted, however, "a state-law claim can involve federal subject matter without involving a substantial federal issue." *Windle v. Synthes USA Prods.*, LLC, 2012 WL 1252550, at *7 (N.D. Tex. Apr. 13, 2012). The invocation of a federal regulatory scheme alone is not enough to create federal jurisdiction. *See RX.com, Inc. v. O'Quinn*, 766 F. Supp. 2d 790, 796 (S.D. Tex. 2011) (Supreme Court's opinions teach that "something more is required" to invoke federal jurisdiction "than the mere fact that the state court will be asked to follow federal standards in the context of adjudicating a state law claim.").

In opposing Plaintiffs' motion to remand, Defendants argue resolution of federal issues is necessary as the theory underlying all but one of Plaintiffs' claims is that AstraZeneca misbranded the Seroquel Franchise in violation of the FDCA, rendering the drugs ineligible for reimbursement under Medicaid, thus interpretation of the FDCA and federal Medicaid statutes is necessary to determine the validity of Plaintiffs' claims. Plaintiffs maintain resolution of federal issues is not necessary because they have also asserted AstraZeneca's conduct violated state law. The Court is not wholly convinced the presence of alternative bases for recovery renders the resolution of federal issues in this action unnecessary. However, the question need not be resolved because the presence of the first requirement under *Grable* and *Singh* alone is not dispositive.

Defendants also maintain the second and third requirements for federal question jurisdiction are satisfied as the federal issue is both actually disputed and substantial. According to Defendants, because the "backbone" of Plaintiffs' claims is whether AstraZeneca engaged in off-label marketing that violated the FDCA, the interpretation of the FDCA is both disputed and substantial. Plaintiffs, in turn, maintain the dispute here is not the legal interpretation of the FDCA, rather the dispute is whether factually AstraZeneca violated federal drug regulations.

The Supreme Court addressed this concept in *Grable*, noting while "violation of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings," that was insufficient to transform those proceedings into matters to be litigated in federal court. *Grable*, 545 U.S. at 318-19. *See also Singh*, 538 F.3d at 338-39 (rejecting argument that state malpractice claim based on conduct of attorney in federal trademark action presented disputed and substantial federal issue because dispute was predominantly one of fact). According to Defendants, the federal issue is "disputed" because they dispute Plaintiffs' ability to recover based on the allegations that promotion of use of the Seroquel Franchise in child and adolescent population is "misbranding" because such uses were in fact medically indicated. This dispute, however, is not one of law as the parties agree medically indicated uses are not off-label and do not constitute misbranding. Rather, Defendants' argument points to a factual dispute concerning whether the Seroquel Franchise was medically indicated for use in child and adolescent populations.

Defendants also maintain there is a disputed and substantial issue of federal law because Plaintiffs are seeking disgorgement of the revenues from reimbursements for Seroquel prescriptions from AstraZeneca's alleged off-label promotion of the Seroquel Franchise. Defendants argue the heart of this request will require resolution of issues of federal Medicaid law and the propriety of prescription drug reimbursement thereunder. Defendants rely on a case in which the court denied remand of a case asserting state law claims by a state attorney general that a drug manufacturer "devised elaborate schemes" for marketing prescription medication for

"off-label" uses. The court found federal jurisdiction existed because the question of the state's obligation to reimburse its insured for prescriptions drugs, using funds largely provided by the federal government, is essential to the state's theory of damages and presents an unavoidable central and disputed federal issue. *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 398378, at *3-4 (E.D.N.Y. Feb. 12, 2008).

As Plaintiffs point out, the judge in the *Zyprexa* case recognized there is a split of authority, noting federal district courts in four other states had remanded virtually identical cases. *Id*. at *4. Moreover, the Court finds the analysis in the *Zyprexa* case flawed in part. Specifically, the court's conclusion that the claim that marketing Zyprexa for off-label uses constituted a violation of federal law "necessarily raise[d] substantial federal questions" appears contrary to Supreme Court precedent. *See Grable*, 545 U.S. at 318-19 (noting negligence allegation resting on violation of federal statutes or regulations would be insufficient to transform proceedings into matters to be litigated in federal court); *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986) (complaint alleging violation of federal statute as element of state cause of action does not state claim "arising under" federal law, rejecting argument that unsettled question regarding application of FDCA to foreign sales raised substantial federal question).

The Court thus concludes Defendants have failed to point to a disputed and substantial federal issue requiring resolution in this case. Absent such an issue, Defendants have failed to establish federal question jurisdiction. This conclusion is in line with other decisions of federal district courts in the Fifth Circuit. *See Louisiana v. Pfizer, Inc.*, 2014 WL 3541057 (M.D. La. July 17, 2014) (remanding case asserting state law claims based on allegations that drug manufacturer engaged in extensive scheme to deceptively and deliberately conceal drug's true efficacy to mislead State and healthcare providers); *Windle*, 2012 WL 1252550, at *7-8 (allegations that medical device marketing violated multiple federal requirements, circumvented warning process required by FDA, and included labeling in direct violation or contravention of FDA requirements not

sufficient to confer federal question jurisdiction); *Caldwell ex rel. Louisiana v. Bristol Myers-Squibb Sanofi Pharm. Holding P'ship*, 2012 WL 3866493 (W.D. La. Sept. 4, 2012) (adopting report and recommendation) (remanding case brought by state attorney general alleging defendant drug manufacturer used false and misleading advertising to promote sale of drug, resulting in state's purchase of drug for Medicaid recipients to whom drug should not have been prescribed); *In re Vioxx Products Liab. Litig.*, 843 F. Supp. 2d 654, 669 (E.D. La. 2012) (declining to find federal question jurisdiction where allegations invoked conduct regulated by FDA); *McAdams v. Medtronic, Inc.*, 2010 WL 3909958, at *4 (S.D. Tex. Sept. 29, 2010) (concluding question of whether medical device manufacturer complied with FDA standards with respect to device was important to parties, but did not implicate substantial federal interest). *See also Williams v. Edcare Mgmt., Inc.*, 2008 WL 4755744, at *8 (E.D. Tex. Oct., 28, 2008) (remanding case, finding reference to alleged violations of federal Medicare laws, in support of state law causes of action not sufficient to raise substantial questions of federal law). Accordingly, this case should be remanded to Texas state court.

IV. CONCLUSION

The Court hereby **GRANTS** Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447 (Clerk's Dkt. #17).

IT IS THEREFORE ORDERED that this cause is **REMANDED** to the 353rd Judicial District Court of Travis County, Texas.

SIGNED on March 30, 2015.

ROBERT L. PITMAN
UNITED STATES DISTRICT JUDGE